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December 27, 2005

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket number 2005D-0330, Collection of Platelets by Automated Methods

Dear Sir or Madam,

Thank you for the opportunity to respond to the draft guidance document noted above. As an independent, community based blood bank, we are concerned about some of the proposed changes in this document. 100% of our platelet inventory is maintained through single donor platelets. These changes, if implemented, would have a significant impact on the availability of platelets in our area.

In addition to our concerns outlined below, we respectfully request a public forum where the proposed changes could be discussed.

Below is an outline of our concerns:

I. Test donors for WBC count prior to the first donation (p.5.III.A)

Recommendation to test donor WBC before the first donation seems arbitrary. No recommendation has been given for acceptable ranges. Without additional WBC counts for comparison, information would not be useful.

II. Non-Steroidal Anti-inflammatory Drugs (p.5.III.A)

Drug category of NSAIDS includes a wide variety of drugs that do not affect platelets in the same manner. We suggest maintaining a 24-hour deferral with the option for longer deferrals for some drugs based on Medical Director discretion.

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III. Perform a Pre-Donation Platelet Count (p.5.III.B)

a. This is not always feasible (i.e. mobile collection sites and smaller fixed sites). Since the stated concern is to more accurately set target platelet yield parameters, donor history can also be used to set these parameters.

b. Using a post-count from a previous donation, without any calculation to estimate a pre-donation level, would likely result in product yields higher than expected and possibly not meeting manufacturers yield/volume requirements.

c. Deferring donors whose platelet counts are less than 150,000 – donors whose last donation was more than 8 weeks ago should not require verification that platelet count has returned to 150,000. Verification should only be required if less than 8 weeks has elapsed since the last donation.

IV. Donation Frequency (p.6.III.B.2)

a. Changing the limit of 24 donations per year to 24 components per year is not necessary. Donors who are able to donate multiple component products typically have higher platelet counts. This change would have a significant, negative impact on platelet inventory. Verifying platelet pre-count and/or post-count levels meet minimum requirements of 150,000, as is the current standard, will better serve to ensure donor safety than limiting the number of components collected in 12 months.

b. Changing the donation frequency for double and triple products to 7 and 14 days respectively is not necessary. The current guidelines of a 2-day interval / no more than 2 times in 7 days / no more than 24 times per year is sufficient (along with platelet count monitoring) to ensure donor safety.

V. Total Volume Loss Per Collection Procedure (p.7.III.B.4)

The proposed change is for the total volume loss per collection not to exceed 500/600 mls based on donor weight or the volume described in the labeling device, "whichever is less". The Baxter Amicus device was cleared for 600/700mls. Since the proposed volume of 500/600 falls into the "whichever is less" statement in the draft document, users of this device would not be allowed to collect the volumes for which it was originally cleared.

VI. Medical Coverage (p.7.III.D)

Requiring a physician to be able to arrive at the premises within 15 minutes would significantly restrict donation locations without increasing donor safety. Emergency First Responders (911) have the training AND equipment needed to treat donors, as well as transport them to an emergency medical facility, in the few cases this is necessary.

VII. Information Provided to the Donor (p.7.IV)

It should be the institution's responsibility to know and track the number of procedures / components / volume allowed per year and to have sufficient controls in place to ensure these limits are not exceeded. Providing this information to donors would not serve any purpose since it should not be their responsibility to ensure they do not exceed these requirements. In addition, these requirements would be far too complicated for many lay donors to decipher or have much interest in.

VIII. Component Collection (p.8.V)

Target yield – Suggested target yields for all products should be set by the institution. Device collection efficiency, platelet counting method, and individual instrument performance all need to be considered when determining these values. Once target values are determined, room must be given to adjust these based on donor history since not all donors yield the same value.

IX. Process Validation (p.11.VI.D)

Statements in this section of the document are conflicting and confusing. Criteria listed for Product Performance Qualification needs clarification as follows:

a. Number of products to be tested – Does this mean 60 singles, and 30 doubles, and 20 triples? This is a very large number.

b. Are these numbers the totals for each type of instrument or for each individual instrument?

c. Once the initial Process Validation is performed, are new instruments of the same type subject to the numbers in a. above or are the new instruments subject to monthly QC only?

d. Testing of components during all phases of the dating period will have a significant impact on product availability, especially in light of the large numbers proposed for product testing.

e. Table I:

   i. Residual WBC count limit of $<5.0 \times 10^6$ per therapeutic dose should not be changed to "per collection". This would create an inconsistency without any bearing on recipient safety. If a single product can have a limit of $<5.0 \times 10^6$ WBC's per dose, then each component of a double or triple product should have the same standard, since they all actually become a "single", or "one" product.

   ii. Volume – Recommendation is for double and triple products to meet additional volume limits of 50% +/-5% and 33% +/-3% respectively. Consideration should be given to manufacturer set yield / volume requirements (i.e. If a product does not meet the 50% +/-5% requirement, but does meet the manufacturer yield / volume requirements in each bag, then the product should be acceptable for issue provided it is labeled properly). Additionally, p.20 addresses this issue again, but also states "or per manufacturer's specifications".

The items in this section do not allow for establishments to develop their own validation criteria based on manufacturer recommendations.

X. Actual Platelet Yield (p.15)

Document states that the yield from each collection should be "provided" to the transfusion facility. P.22 states that the actual yield "should be made available to the transfusion service". These statements are contradictory. The Circular of Information addresses this issue and should be sufficient.

XI. QC Monitoring (p.19.VII.C.2)

a. Period for testing of products is unclear. First paragraph states for testing to be "at the end of the storage period" which includes "testing at the time of issue". Second bullet from bottom of page states to "allow for testing at the maximum allowable storage time". This needs clarification.

b. QC Protocol (p.20 1st bullet) – Statement to "test for component retention". Does this apply only to filter methods? If so, this should be stated.

c. QC Protocol (p.20 7th bullet) – This statement suggests that you may test just one part of a double or triple product for platelet yield and pH. This seems a departure from the more strict standards proposed throughout this document, especially since bullet 11 requires testing of each component.

XII. Quality System Audits (p.21)

Document describes checking the tare weights of empty containers/tubing and performing an actual tared weight. This does not allow for following manufacturer's recommendation of calculating a tare weight based on bag configuration and known weights per item as provided by the manufacturer.

Thank you for allowing us the opportunity to comment of this draft guidance.

Sincerely,

Scott W. Hall, M.D.
Medical Director